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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,336	02/02/2001	John H. Stevens	004-C4	1406

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EXAMINER	
NGUYEN, ANH TUAN TUONG	
ART UNIT	PAPER NUMBER
3763	4

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,336	STEVENS ET AL.	
	Examiner	Art Unit	
	Anh-Tuan T. Nguyen	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola (4,985,014) in view of Schock et al (5,254,097).

Orejola discloses a cardiopulmonary bypass catheter system (see abstract and Figs. 1 & 2) for withdrawing fluid from either the right or left ventricles comprising a return cannula (54) having an elongated cannula body, a distal end, a proximal end, a return lumen (see Fig. 6), a return outlet (68) and a return inlet (see Fig. 6), and a catheter port (50); an occlusion catheter (52) slidably and removably positioned through the catheter port (via Seldinger technique - see col. 3, lines 53-55) having an infusion lumen with an infusion inlet and an infusion outlet (66), and a balloon (48).

However, Orejola does not specifically disclose the use of a hemostasis valve in combination with the catheter port in order to allow relative movement between fluid inlet (12) and fluid outlet (14).

On the other hand, Schock et al disclose an access cannula for use with a percutaneously cardiopulmonary bypass system including the well-known use (2:35-38) of a hemostasis valve (144) in order to allow movements between an inner and an outer tubes or catheters. Schock et

al also disclose that a vented fitting or port (24) to be used with an infusion lumen while connecting to a pump (7:62-67) in order to provide extracorporeal cardiopulmonary bypass procedure (4:29-36). With respect to claim 12, Schock et al disclose in Figure 6 a venous cannula positionable in a vein and an oxygenator fluidly coupled to the venous cannula via the pump, and that the oxygenator being fluidly coupled to the return inlet (220 in order to complete a cardiopulmonary bypass.

Therefore, it would have been obvious to one skilled in this art to modify the invention to Orejola to include (a) a hemostasis valve in combination with a catheter port in order to allow movement between the inlet cannula (12) and the outlet cannula (14); and; (b) a venting port in communication with the infusion lumen in the event that the inlet cannula and outlet cannula do not have to be necessarily and strictly only in closed-loop communication in order to allow the introduction of oxygen or other sources, such as cardioplegic fluid, into the blood before reintroducing it back into to body, during the bypass procedure, as taught to be desirable in Schock et al.

With respect to claims 3-5, and 9-11, Orejola in view of Schock et al disclose the invention substantially as claimed except for the specific size of the lumen and the pressure that the lumen is adapted to provide. It would have been an obvious matter of design choice to modify the invention to Orejola in view of Schock et al to include the cross-sectional area of about 4.5 mm^2 in order to obtain a more controllable flow rate, since such a modification would have involved a mere change in the size of a component; and; a pressure at any desired rate depending on the size of the patient and the need to deliver blood or cardioplegic fluid at that desired rate. A change in size is generally recognized as being within the level of ordinary skill

in the art, e.g., see Buckberg et al at column 6, lines 46-48 or column 7, lines 7-36. *In re Rose*, 105 USPQ 237 (CCPA 1955).

3. Claims 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola in view of Schock et al as applied to claim 1 above, and further in view of Buckberg et al (5,011,469).

Orejola in view of Schock et al disclose the invention substantially as claimed except for the use of a pressure lumen with the occlusion catheter with a pressure outlet distal to the balloon and a pressure port proximal to the balloon. Orejola in view of Schock et al also do not specifically disclose the use of separate return pump and venting pump.

Buckberg et al disclose the invention substantially as claimed including the use of various pressure transducers in order to monitor various pressures (12:48-63), and, the use of a return pump coupled to the return in let for pumping oxygenated blood while the heart is arrested, and a venting pump couple to a venting port for withdrawing fluids from the ascending aorta through the infusion lumen (Fig. 9) when the inlet cannula and the outlet cannula do not have to be in closed-loop communication in order to oxygenate and/or treat the blood.

It would have been obvious to one skilled in this art to modify the invention to Orejola in view of Schock et al to further include a pressure transducer in the aorta in order to monitor pressure there; or; to include the use of separate return pump and venting pump in order to further oxygenate the blood before reintroducing it back to the patient, as taught to be desirable in Buckberg et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anh-Tuan T. Nguyen whose telephone number is 703-308-2154. The examiner can normally be reached on Mon-Fri, 0830-1800 hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are available upon request.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Anh-Tuan T. Nguyen
Primary Examiner
Art Unit 3763

ATN
August 12, 2002